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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,339	09/10/2002	Paul Sherwood	13596-003US1	2886

7590 02/17/2004

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,339	SHERWOOD ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/6/03*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *082203* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 10-26 are pending in this application.

Priority

Priority to PCT/GB00/03490 filed September 12, 2000 and United Kingdom Application Number 9921985.9, filed September 16, 1999, has been acknowledged.

Response to Applicant's Arguments/Amendment

Claim Rejections - 35 USC § 112

Applicant's amendment filed November 6, 2003, to the rejection of claims 10-24 under 35 U.S.C. 112, second paragraph has made the said rejection moot. Therefore, the rejection has been withdrawn.

Claim Rejections - 35 USC § 102

Applicant's arguments filed November 6, 2003, to the rejection of claims 10-15 and 20 under 35 U.S.C. 102(b) as being anticipated by Hyodo et al., 5,260,289 have been fully considered; however, they have not been found convincing. Therefore, the said rejection has been MAINTAINED for the reasons set forth in Paper No. 8 and those found below.

Applicant argue that although Hyodo discloses a method of alleviating pain by injecting a composition comprising calcium pantothenate, Hyodo lacks enablement for treating pain using calcium pantothenate because the reference does not provide any indication that calcium pantothenate, in the absence of the "active ingredients", can be used in methods of treating inflammation or pain.

This is not found convincing because Hyodo does teach an injectable composition and method of using same, which comprises calcium pantothenate. The reference specifically teaches "specific examples" of pain that can be treated with the composition and teaches frozen shoulder as a "specific example," thus meeting the limitation of instant claim 11. Moreover, the instantly claimed methods do not preclude additional "active ingredients" form being administered with calcium pantothenate. Finally, the reference clearly teaches that an injection of Neo Vitacain, which comprises calcium pantothenate, is useful for the treatment of pain.

In response to applicant's argument that Hyodo does not indicate calcium pantothenate as being useful in treating inflammation, the examiner respectfully reminds applicant that claim 10, the only independent claim in the instant application, and the only claim that claims a method of alleviating inflammation, is written in the alternative. Thus, the method of treating pain, as taught by Hyodo, clearly anticipates instant claims 10-15 and 20.

Therefore, the rejection has been MAINTAINED.

Claim Rejections - 35 USC § 103

Applicant's arguments filed November 6, 2003, to the rejection of claims 10-16 and 20-21 and 20 under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al., 5,260,289 and further in view of UK Patent Number 1,145,623 (623) have been fully considered; however, they have not been found convincing. Therefore, the said rejection has been MAINTAINED for the reasons set forth in Paper No. 8 and those found below.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Hyodo teaches a method of using a composition comprising NEO VITICAN™, which comprises 100-mg/100 ml of calcium pantothenate and 100 mg/100ml of dibucaine hydrochloride (a local anesthetic), for the local treatment of pain and the 623 reference teaches calcium d-pantothenate has previously been reported for the alleviation of arthritis and that greatly improved results are obtained in the treatment of osteoarthritis when pantothenate and cysteine are administered together.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of pain treatment as taught by Hyodo et al, by using pantothenic acid in combination with cysteine, as taught by 623 because of the reasonable expectation of obtaining a method of locally treating rheumatic pain with a combination of medicaments which have greatly improved results when administered together.

In response to applicant's argument that the combined references lack the treatment of inflammation, the examiner respectfully reminds applicant that claim

10, the only independent claim in the instant application, and the only claim that claims a method of alleviating inflammation, is written in the alternative. Thus, the method of treating pain meets the specific limitations of instant claims 10-16 and 20-21.

Applicant's arguments filed November 6, 2003, to the rejection of claims 10-24 under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al., 5,260,289 taken with UK Patent Number 1,145,623 (623) and further in view of Rozenberg, RU 2078564C1 have been fully considered; however, they have not been found convincing. Therefore, the said rejection has been MAINTAINED and being applied to newly added claims 25-26 for the reasons set forth in Paper No. 8 and those found below.

Applicants argument that the intended function of DPPC in Applicants' claimed method is distinct and different from that disclosed in Rozenberg; and therefore, one of skill in the art are would not be motivated to combine the teachings of Rozenberg, with those of the 623 Patent and Hyodo to arrive at Applicants' claimed method has not been found convincing because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Rozenberg teaches compositions comprising dipalmitoyl phosphatidylcholine for the treatment of septic inflammations and that they can

be treated more effectively by administering glucocorticoids whose anti-inflammatory effects have been enhanced by incorporating them in a liposome membrane dipalmitoyl phosphatidylcholine. The Rozenberg reference teaches the compositions as being useful for treating inflammatory diseases such as rheumatoid arthritis and that acute inflammation symptoms are alleviated after a single injection without side-effects by using only 1/3 of the dosage associated with finely-crystalline hydrocortisone forms. See: abstract.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating pain as taught by the combined references above by adding phospholipids such as dipalmitoyl phosphatidylcholine as taught by Rozenberg because of the reasonable expectation of obtaining a method of treating pain and inflammation by with a liposomal membrane that would allow injection of the composition without side effects, using a lesser amount of active ingredients. The mere description in applicants specification that the phospholipids are believed to act as a lubricant in joints, taking over to some extent the function of sinovial fluid does not result in a structural difference between the claimed invention and the prior art. Therefore, the said rejection has been MAINTAINED,

MAINTAINED CLAIM REJECTIONS

Claim Rejections - 35 USC § 102

Claims 10-15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyodo et al., 5,260,289.

Hyodo et al teach a method of using a composition comprising NEO VITICAN™, which comprises 100 mg/100 ml of calcium pantothenate and 100 mg/100ml of dibucaine hydrochloride (a local anesthetic), for the local treatment of pain; thus, meeting the specific limitations of instant claims 10-13, 15 and 20. See: col. 1, lines 11-50 and abstract. The reference teaches that the composition is useful for the treatment of chronic rheumatism, low backache, backache, frozen shoulder, thus meeting the disorder limitations of instant claim 11 and that the composition is injected locally into mammals. See: col. 2, lines 35-51; col. 3, line 19 – col. 4, line 7; col. 5, line 12 – col. 6, line 68. Finally, the reference teaches that the compositions are prepared into injections when in use and gives an aqueous solution as an example of how the compositions may be prepared. See: col. 3, lines 46-66. Therefore, Hyodo et al clearly anticipate the instantly claimed limitations of claims 10-15 and 20.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-16 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al., as applied to claims 10-15 and 20 above, and further in view of UK Patent Number 1,145,623 (623).

Hyodo et al teach a method of using a composition comprising NEO VITICAN™, which comprises 100-mg/100 ml of calcium pantothenate and 100 mg/100ml of dibucaine hydrochloride (a local anesthetic), for the local treatment of pain. See: col. 1, lines 11-50 and abstract. The reference teaches that the

composition is useful for the treatment of chronic rheumatism, low backache, backache, frozen shoulder, thus meeting the disorder limitations of instant claim 11 and that the composition is injected locally into mammals. See: col. 2, lines 35-51; col. 3, line 19 – col. 4, line 7; col. 5, line 12 – col. 6, line 68. Hyodo et al teach that the compositions are prepared into injections, when in use, and gives an aqueous solution as an example of how the compositions may be prepared. See: col. 3, lines 46-66.

However, the primary reference lacks the cysteine or glucosamine of instant claim 16 and 21.

623 teaches compositions useful in the treatment of osteoarthritis and rheumatoid arthritis. The secondary reference teaches a composition comprising d-pantothenic acid and cysteine for parenteral administration. The 623 reference also teaches that although it has previously reported to use calcium d-pantothenate for the alleviation of arthritis, greatly improved results are obtained in the treatment of osteoarthritis, when pantothenate and cysteine are administered together.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of pain treatment as taught by Hyodo et al, by using pantothenic acid in combination with cysteine, as taught by 623 because of the reasonable expectation of obtaining a method of locally treating rheumatic pain with a combination of medicaments which have greatly improved results when administered together.

Claims 10-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyodo et al taken with UK Patent Number 1,145,623 (623), as applied to claims 10-16 and 20-21 and further in view of Rozenberg, RU 2078564C1.

Rozenberg teaches compositions comprising dipalmitoyl phosphatidylcholine for the treatment of septic inflammations and that they can be treated more effectively by administering glucocorticoids whose anti-inflammatory effects have been enhanced by incorporating them in a liposome membrane dipalmitoyl phosphatidylcholine. The reference teaches the compositions as being useful for treating inflammatory diseases such as rheumatoid arthritis and that acute inflammation symptoms are alleviated after a single injection without side-effects by using only 1/3 of the dosage associated with finely-crystalline hydrocortisone forms. See: abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating pain as taught by the combined references above by adding phospholipids such as dipalmitoyl phosphatidylcholine as taught by Rozenberg because of the reasonable expectation of obtaining a method of treating pain and inflammation by with a liposomal membrane that would allow injection of the composition without side effects, using a lesser amount of active ingredients.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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